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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,339	07/09/2001	Mai H. Nguyen	30448.78USU1	6039

26941 7590 09/13/2002

MANDEL & ADRIANO  
55 SOUTH LAKE AVENUE  
SUITE 710  
PASADENA, CA 91101

EXAMINER
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DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/13/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/901,339

Applicant(s)

NGUYEN, MAI H.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 17 June 2002.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's election with traverse of Group I, claims 1-7 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the invention of Groups I and II are essentially the same, a search of Group I is applicable to Group II-III. This is found to be persuasive. Groups II-III will be joined with elected Group I, claims 1-11 will be examined.

#### ***Information Disclosure Statement***

2. The information disclosure statement filed 18 March 2002 has been considered. A signed copy is attached hereto.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen, (1997, Investigational New Drugs, 15:29-37) in view of Relf, et al.,(1997, Cancer Research, 57(5):963-3), Li, et al (1994, The Lancet, 344: 82-86), Cheales-Siebenaler, et al., (1999, Journal of Human Lactation, 15(1):41-3), and Petrakis, (Epidemiologic Reviews, 1993, 15(1):188-93).

Nguyen teach angiogenic factors, such as FGF, as tumor markers. Nguyen show abnormal FGF expression in bodily fluids of patients with breast tumors (p. 30, Table 1) and an elevated level of bFGF in the urine of patients with breast tumors (p. 30, col. 2). Nguyen further teach a good correlation between serum levels of bFGF and tumor, size, grade and invasion (p. 30, col. 2). Nguyen does not teach measuring bFGF in a test sample from nipple fluid.

Relf teach detection of bFGF using ELISA and increased bFGF expression in tumors than in normal breast tissue.

Li teach the detection of bFGF in the CSF of patients with brain tumors, but not in controls. Detection of bFGF was determined using immunoassay with antibodies against a specific epitope of bFGF.

Petrakis teach nipple aspirate fluid contains several types of exfoliated breast cells including epithelial (p. 188, col. 2) and nipple aspirated breast fluid can provide information on the character of the breast epithelium (p. 190, col. 1).

Given the teachings of Nguyen and Li, it would have been obvious at the time of the invention to diagnose and determine the progress of breast cancer since Nguyen teach elevated levels of bFGF in patients with breast tumors and a good correlation between serum levels of bFGF and tumor, size, grade and invasion and to detect bFGF levels using immunoassay as taught by Li. Likewise, it would have been obvious to one of ordinary skill in the art to measure bFGF in nipple breast fluid since Petrakis teach that nipple fluid contains several types of exfoliated breast cells and Relf teach the detection of increased levels bFGF in breast tumor tissue as compared to normal breast tissue. Furthermore, it would be obvious to use an assay kit for bFGF detection and to use oxytocin to enhance the flow of nipple fluid (Cheales-Siebenaler).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD  
September 10, 2002

*Sheela J. Huff*  
SHEELA HUFF  
PRIMARY EXAMINER